



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

November 6, 2008

MEMORANDUM:

Subject: EPA Reg. No.: 6218-71 / Summit Year-Round Spray Oil  
DP Barcode: 357170  
Case No.: 3004

From: John L. Dupuy Ph.D, Pathologist  
Product Reregistration Branch  
Special Review and Reregistration Division (7508P)

*[Handwritten signature]* 11/10/08

To: Veronica Dutch, CRM  
Product Reregistration Branch  
Special Review and Reregistration Division (7508P)

Applicant: Summit Chemical Company  
235 South Kresson Street  
Baltimore, MD 21224

FORMULATION FROM EPA Reg. No. 6218-71 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Petroleum Oil.....	98.8%
<u>Inert Ingredient(s):</u> .....	1.2%
	100.00%

Contains Petroleum Distillates

BACKGROUND: In the 8 month response to the Aliphatic Solvents RED, the registrant has submitted acute toxicity studies to support the reregistration of their product, EPA Reg. No. 6218-71. The MRID's are as follows: 475294-03 (81-1), 475294-06 (81-2), 475294-02 (81-3), 475294-05 (81-4), 475294-04 (81-5), 475294-01 (81-6). The studies were conducted by Product Safety Labs and the test material used was the subject product.

RECOMMENDATIONS:

- The acute toxicity studies submitted are acceptable to support the reregistration of EPA Reg. No. 6218-71.

The acute toxicity profile for EPA Reg. No. 6218-71 is currently:

Acute Oral	IV	Acceptable
Acute Dermal	IV	Acceptable
Acute Inhalation	IV	Acceptable
Primary Eye	IV	Acceptable
Primary Dermal	IV	Acceptable
Skin Sensitization	non-sensitizer	Acceptable

NOTE: The acute toxicity requirements have been satisfied for the subject product.

**DATA REVIEW FOR ACUTE ORAL TOXICITY (§81-1, 870.1100)**

**Product Manager:** Venus Eagle, I  
**MRID No.:** 475294-03

**Reviewer:** John L. Dupuy Ph.D  
**Study Completion Date:** 7/9/08  
**Report No.:** 24743

**Testing Facility:** Product Safety Labs  
**Author:** G. Moore

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** Summit Year-Round Spray Oil, clear light- yellow liquid  
**Species:** Sprague-Dawley derived albino rat  
**Age:** young adult  
**Weight:** females = 164 – 195 g  
**Source:** Ace Animals, Inc.

**Conclusion:** (Up and Down Method)

1. **LD<sub>50</sub> (mg/kg):** >5000 mg/kg

2. **Toxicity Category:** IV

**Classification:** Acceptable

**Procedure (Deviations from §81-1):** none

**Results:** Limit Test

Test Sequence	Animal Id	Dose Level (mg/kg)	Short term outcome	Long term outcome
1	3101	5000	S	S
2	3102	5000	S	S
3	3103	5000	S	S

S = survival; D = death

**Observations:** Two females had ano-genital staining on day 1. From day 2 all were active and healthy. All gained weight during the study.

**Gross Necropsy:** No gross abnormalities.

**DATA REVIEW FOR ACUTE DERMAL TOXICITY (§81-2, 870.1100)**

**Product Manager:** Venus Eagle, 1  
**MRID No.:** 475294-06

**Reviewer:** John L. Dupuy Ph.D  
**Study Completion Date:** 7/8/08  
**Report No.:** 24744

**Testing Facility:** Product Safety Labs  
**Author:** G. Moore

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** Summit Year-Round Spray Oil, clear light- yellow liquid  
**Species:** Sprague-Dawley derived albino rat  
**Weight:** males = 219 – 257 g; females = 188– 208 g  
**Age:** young adult  
**Source:** Ace Animals, Inc.

**Summary:**

1. **LD<sub>50</sub> (mg/kg):** > 5000 mg/kg

2. **Toxicity Category:** IV

**Classification:** Acceptable

**Procedure (Deviations From §81-2):** none

**Results:**

**Reported Mortality**

Dosage (mg/kg)	(number deaths/number tested)		
	Males	Females	Combined
5000	0/5	0/5	0/10

**Observations:** Twenty four hours prior to application of the test material, the dorsal area and trunks were clipped free of hair. The test substance was applied to a 2 x 3 inch intact dose site (approximately 10 % of the body surface) and covered with a 2 inch x 3 inch, 4-ply gauze pad. The pad and entire trunk of each animal were then wrapped with semi-occlusive 3-inch Durapore tape. After 24 hours the pads and wrappings were removed and the test sites were gently cleansed. All animals gained body weight, and all appeared active and healthy during the study. There were no signs of dermal irritation, gross toxicity, or abnormal animal behavior.

**Gross Necropsy Findings:** No observable abnormalities were noted.

**DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)**

**Product Manager:** Venus Eagle, I  
**MRID No.:** 475294-02

**Reviewer:** John L. Dupuy Ph.D  
**Study Completion Date:** 7/17/08  
**Report No.:** 24745

**Testing Facility:** Product Safety Labs  
**Author:** G. Moore

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** Summit Year-Round Spray Oil, clear light- yellow liquid  
**Species:** Sprague-Dawley derived albino rat  
**Weight:** males = 234 – 258 g; females = 190 – 209 g  
**Age:** young adult  
**Source:** Ace Animals, Inc.

**Summary:**

1. **LC<sub>50</sub> (mg/L):** > 2.07 mg/L
2. **MMAD:** 2.1 µm                      **GSD:** 1.93
3. **Tox. Category:** IV                      **Classification:** Acceptable

**Procedure (Deviation From §81-3):** None

**Results:**                      **Reported Mortality**

Exposure Concentration	(number deaths/number tested)		
	Males	Females	combined
2.07 mg/L	0/5	0/5	0/10

Chamber Atmosphere		
Dose Level mg/L	MMAD	GSD
2.07	2.1 µm	1.93
	2.0 µm	1.93

Chamber Environment	Dose Level mg/L
	2.07
Chamber Volume	6.7 L
Airflow	25.6-25.8 Lpm
Temperature (°C)	21-23
Relative Humidity %	48-54

**Clinical Observations:** All gained weight and were active and healthy

**Gross Necropsy Findings:** No gross abnormalities were noted

**DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)**

**Product Manager:** Venus Eagle, 1  
**MRID No.:** 475294-05

**Reviewer:** John L. Dupuy Ph.D  
**Study Completion Date:** 7/8/08  
**Report No.:** 24746

**Testing Facility:** Product Safety Labs  
**Author:** G. Moore

**Quality Assurance (40 CFR §160.12):** Included

**Test Material** Summit Year-Round Spray Oil, clear light- yellow liquid

**Dosage:** 0.1 ml

**Species:** New Zealand albino rabbit

**Sex:** 3 males

**Weight:** Not given

**Age:** Young adult

**Source:** Robinson Services Inc.

**Summary:**

**Toxicity Category:** IV

**Classification:** Acceptable

**Procedure (Deviations From §81-4):** none

**Results:**

Observations	(number "positive"/number tested)									
	Hours					Days				
	1	24	48	72		4	7			
Corneal Opacity	0/3	0/3	0/3	0/3						
Iris	0/3	0/3	0/3	0/3						
Conjunctivae										
Redness	3/3	0/3	0/3	0/3						
Chemosis	0/3	0/3	0/3	0/3						
Discharge	2/3	0/3	0/3	0/3						

Prior to instillation, 2-3 drops of ocular anesthetic (tetracaine hydrochloride ophthalmic solution, 0.5%) were placed in both eyes of each animal.

At 1 hr., 3/3 diffuse crimson red conjunctivae and 2/3 discharge with moistening of the hairs just adjacent to the lids. All animals were free of ocular irritation by 24 hours.

**DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)**

**Product Manager:** Venus Eagle, 1

**MRID No.:** 475294-04

**Reviewer:** John L. Dupuy Ph.D

**Study Completion Date:** 7/8/08

**Report No.:** 24747

**Testing Facility:** Product Safety Labs

**Author:** G. Moore

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** Summit Year-Round Spray Oil, clear light- yellow liquid

**Species:** New Zealand albino rabbit

**Dosage:** 0.5 ml

**Age:** young adult

**Sex:** 3 males

**Weight:** not given

**Source:** Robinson Services, Inc.

**Summary:**

**1. Toxicity Category:** IV

**PII = 0.2**

**2. Classification:** Acceptable

**Procedure (Deviations From §81-5):** none

**Results:** Twenty four hours prior to application of the test material, the dorsal area and trunks were clipped free of hair. The test material was applied to one 6-cm<sup>2</sup> intact dose site on each animal and covered with a 1x1 inch gauze pad. The pads and trunks were then wrapped with 3 inch Micropore tape. After 4 hours the pads and wrappings were removed and the test sites were cleansed.

At 1 hr., 2/3 very slight erythema. By 24 hrs, all had cleared of dermal irritation.



**DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)**

**Product Manager:** Venus Eagle, 1  
**MRID No.:** 475294-01

**Reviewer:** John L. Dupuy Ph.D  
**Study Completion Date:** 8/15/08  
**Report No.:** 24748

**Testing Facility:** Product Safety Labs  
**Author:** G. Moore

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** Summit Year-Round Spray Oil, clear light- yellow liquid

**Positive Control Material:** HCA historical control (PSL # 22930, 10-10-07)

**Species:** Hartley albino guinea pig  
**Weight:** males = 416 – 521 g  
**Age:** young adult  
**Source:** Elm Hill Breeding Labs

**Method:** Buchler

**Summary:**

1. **This Product is a non sensitizer**
2. **Classification:** Acceptable

**Procedure (Deviation From §81-6):** none

**Procedure:**

A group of animals were used to determine the highest non-irritating concentration (HNIC) of the test substance prior to the challenge dose. The HNIC for the test substance was determined to be 1.0 % w/w mixture in distilled water.

The test animals were induced with 0.4 ml of the neat test substance once a week for three weeks using a Hill Top Chamber. Twenty four hours after each induction dose the animals were scored for irritation. Two weeks after the last induction dose, 0.4 ml of a 1.0% w/w mixture of the test substance in distilled was used to challenge the test animals. Twenty four and 48 hours after the challenge the animals were evaluated for sensitization.

A group of animals were used as naive controls. These animals received only the challenge doses of the test material.

**Results:**

Twenty four hours after the first induction dose, 10/20 very faint erythema. Twenty four hours after the second induction dose, 4/20 very faint erythema. Twenty four hours after the third induction dose, 10/20 very faint erythema and 1/20 faint erythema.

Twenty four hours after challenge, 4/20 test material-induced animals exhibited very faint erythema.

At 24 hours, in the naive control group of animals challenged with the test material, no dermal reactions were noted.

**LABELING:**

**ID #:** 006218-00071 SUMMIT YEAR-ROUND™ SPORAY OIL

**INGREDIENT STATEMENTS:**

Contains Petroleum Distillates

**SIGNAL WORD:** CAUTION

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS:**

Wear long sleeved shirt, long pants, shoes, and socks.

**FIRST AID:**

**IF SWALLOWED:** Immediately call a poison control center or doctor. Do not induce vomiting unless told to by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**Note to Label Review Team:** No First Aid statements are required due to the toxicity categories. If the registrant wishes to include First Aid statements then they must be the same as listed above.

**USER SAFETY RECOMMENDATIONS:**

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The proposed label must contain the following guidance:

**NOTE TO PHYSICIAN:**

May pose an aspiration pneumonia hazard.

Contains petroleum distillate.